K072639

Attachment #8 – 510(k) Summary

SUMMARY OF 510(k) Submission

NOV 19 2007

A. INFORMATION

1. SUBMITTER'S

NAME: **Shandong Yuyuan Latex Gloves Co., Ltd**

ADDRESS: **1296, Industrial Park, Linqing City, Shandong 252600, China**

TELEPHONE NUMBER: **+86-635-297-1167**

CONTACT PERSON: **Jessie Sun Jing**

DATE SUMMARY PREPARED: **July 2007**

2. NAME OF DEVICE

TRADE OR PROPRIETARY NAME: **Yuyuan Powdered Latex Examination Glove**

COMMON OR USUAL NAME: **Examination Glove**

CLASSIFICATION NAME: **Examination Glove**

3. PREDICATE DEVICE IDENTIFICATION

NAME, NUMBER **N.A.**

4. DESCRIPTION OF DEVICE

a. HOW THE DEVICE FUNCTIONS:
Natural rubber latex films form a barrier to body fluids and bloodborne pathogens

b. SCIENTIFIC CONCEPTS THAT FORM THE BASIS FOR THE DEVICE:
The latex rubber is water tight under normal conditions of use. It's tensile properties cause it to conform to the hand, allowing movements necessary for a medical procedure.

c. PHYSICAL AND PERFORMANCE CHARACTERISTICS SUCH AS DESIGN, MATERIALS AND PHYSICAL PROPERTIES:
Natural rubber latex is known to create a barrier to bloodborne pathogens and body fluids. ASTM conforming tensile properties create a glove that is strong and flexible. The leaching process removes traces of chemical accelerants that may be chemically irritating. The glove is manufactured in accordance with the requirements of ASTM D3578-06 and ASTM D5151 requirements.

K072639

5. STATEMENT OF INTENDED USE, INCLUDING DESCRIPTION OF THE DISEASES OR CONDITIONS THAT THE DEVICE WILL ADDRESS

This is a disposable device, intended for medical purposes, that is worn on the examiner's hand to prevent contamination between patient and examiner. Examination gloves with protein content labeling are suitable in situations where healthcare worker or patient allergic sensitivity may be a factor. Powdered gloves have increased donnability over wet hands.

6. EXPLANATION OF SIMILARITIES OR DIFFERENCES TO PREDICATE DEVICE

N.A.

B. IF SE DECISION BASED ON PERFORMANCE DATA

1. DISCUSSIOM OF NON-CLINICAL TESTS

SPECIFICATION	**Powdered**
PERFORMANCE STANDARDS	**ASTM D3578-06**
WATER TIGHTNESS	**ASTM D5151-92**
PROTEIN	**ASTM D5712-05**

2. DISCUSSION OF CLINICAL TESTS

SPECIFICATION	
SAFETY	
RABBIT IRRITATION	**Passes**
GUINEA PIG SENSITIZATION	**Passes**

3. CONCLUSION DRAWN FROM NONCLINICAL AND CLINICAL TESTS THAT DEMONSTRATE SAFETY EFFECTIVENESS, AND PERFORMANCE

The data summaries indicate that the product meets or exceeds acceptable scores in nonclinical tests, and satisfies the requirements for a safe and effective powdered medical glove.

Pursuant to 21 C.F.R.807.87 (j), I, Jessie Sun Jing, Sales and Marketing Executive of Shandong Yuyuan Latex Gloves Co., Ltd, certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as the Sales and Marketing for Shandong Yuyuan Latex Gloves Co., Ltd, and in reliance thereupon, the data and information submitted in this premarket notification are truthful and accurate and that no facts material to a review of the substantial equivalence of this device have been knowingly omitted from this submission.

Jessie Sun Jing
Sales and Marketing Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 2007

Ms. Jessie Sun
Shandong Yuyuan Latex Gloves Company, Limited
No. 1296 Industrial Park
Linqing City, Shandong
CHINA 252600

Re: K072639
Trade/Device Name: Yuyuan Latex Examination Glove, Powdered
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: November 9, 2007
Received: November 14, 2007

Dear Ms. Sun:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D. for
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.0 **Indications for Use Statement:** Include the following or equivalent Indications for Use page. The information, data and labeling claims in the entire the 510(k) submission must support and agree with the indications for Use Statement.

INDICATION S FOR USE
Applicant: Shandong Yuyuan Latex Gloves Company Ltd
510 (k) Number (if known): New Application K072639
Device Name: "Yuyuan Latex Examination Glove, Powdered"

Indications For Use:

The Yuyuan, Latex Examination Glove is "a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner." (21CFR 880.6250)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH Office of Device Evaluation (ODE)

Sheila N. Murphy M.D.
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072639

Prescription Use_____ OR Over- The-Counter ✓
Per 21 CFR 801.109
(Optional Format 1-2-96)

For a new submission, do **NOT** fill in the 510(k) number blank